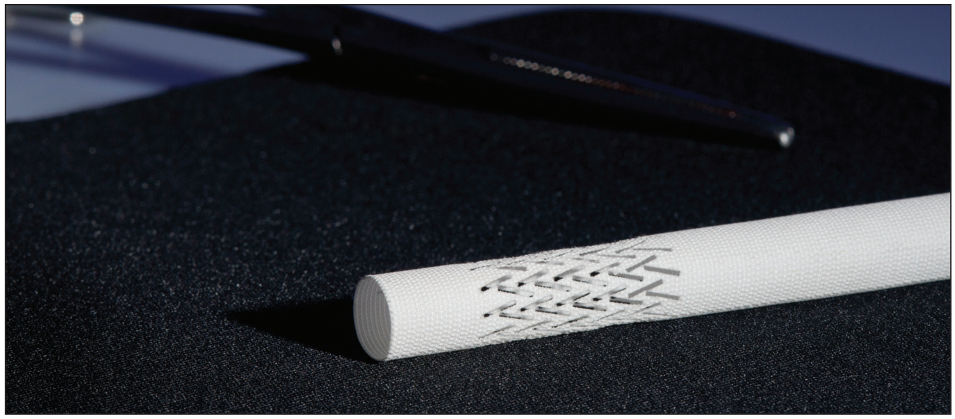
MEDICAL DESIGN BRIEFS

Biomedical Textile Material Selection and Performance Considerations in Device Design

Biocompatible materials are increasingly being refined for incorporation in therapeutic applications.

Secant Medical, Perkasie, PA



A small-diameter woven tube, pictured here, reveals an intricate laser cut pattern. (Photo courtesy of Secant Medical)

Biomedical textile structures incorporate a wide array of biocompatible materials, including advanced polymers and metals in a range of sizes and thicknesses with varying material characteristics and performance properties. Promising substrates, now in development, add to the diversity of biomedical textile structure options. This versatility puts device designers within reach of developing highly complex, ultra-sophisticated components that can be used in a number of therapeutic applications, including orthopedics, cardiovascular, tissue engineering, neurology, and general surgery.

Whether recently introduced or long established, these biomedical materials can elicit one of three possible tissue responses :

- Nearly inert materials for minimal tissue response;
- Bio-active materials that encourage surrounding tissue integration; or
- Degradable (or resorbable) materials that dissolve completely over time.

Bioabsorbable polymers such as polyglycolides and polylactides are being used more frequently in applications associated with non-permanent or hybrid biologic/synthetic repairs and are ideal in tissue engineering and orthobiologics applications requiring short-term tissue support while the body repairs itself, followed by long-term biologic integration. In addition, the inherent chemical inertness and enhanced mechanical properties of advanced polymers such as polyaryletherketone and high-performance polyethylenes, and radiopaque and low-friction polymers are earning approval for a variety of uses.

High-performing, flexible, and soft textiles can now be produced from metals like Nitinol, stainless steel, titanium, and tantalum. Compared to polymer-based textiles, these substrates often exhibit superior mechanical properties for certain applications, while retaining shape transformation properties.

While well-known, established materials generally offer a smoother path to regulatory approval since they have long been used in implants, emerging materials and combinations offer the advantage of being able to fit increasingly detailed design parameters. For example, some textile components can now be engineered to degrade at varying rates over varying time periods; by synchronizing the modulation of fabric absorption with tissue healing, this multi-phased structural degradation promotes a more biologic repair.

A combination of established and emerging substrates, along with a carefully structured material selection process, offers an effective path toward enhancing the performance of a finished device. However, the wide variety of therapeutic areas, as well as the mechanical and physiological characteristics desired for the finished device, must always be used to guide decisions about textile material composition and supplier.

Each fabric-forming technology — weaving, braiding, and knitting — has its own set of advantages, limitations, and varying levels of compatibility with the different material substrates available. The selection process involves:

- Identification of an application-appropriate material, or combination of materials, for the textile structure;
- Laboratory and clinical analysis to ensure that biocompatibility, tissue response, and other long-term durability parameters are within specification;
- Development of detailed specifications and controls related to material composition;
- Follow-on supply chain management to ensure quality, availability of materials, and execution of appropriate supply agreements; and
- Finally and significantly, the forming process that will be used to manufacture the textile structure. In this area, the expertise of biomedical textile producers should determine the orientation of the biomaterials in an engineered structure that balances the physical and mechanical performance of both the fabric geometry and the biomaterial itself.

Because material selection lies squarely at the intersection of the physical, chemical, and biological sciences, a multi-disciplinary team of engineers from each of these areas should be involved early in the development process when evaluating options, whether on the side of the device manufacturer or the biomedical textile manufacturer (or a combination of both).

This technology was done by Secant Medical, Perkasie, PA. For more information, visit ***http://info.hotims.com/34452-161***.